

# EMULSION POLYMERS COUNCIL, INC.

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Dockets Management Branch (HFA-305)  
Attention Docket Numbers 02N-0276; 02N-0278  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852  
[www.fda.gov/dockets/ecomments](http://www.fda.gov/dockets/ecomments)

Re: EPC Comments on the Proposed Regulation on Registration of Food Facilities and Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [Docket No. 02N-0276; 02N-0278]

To Whom It May Concern:

On behalf of the Emulsion Polymers Council (EPC), I am pleased to submit comments on the U.S. Food and Drug Administration's (FDA) proposals concerning the Registration of Food Facilities (68 Fed. Reg. 5378) and Prior Notice of Imported Food (68 Fed. Reg. 5428) Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act").<sup>1</sup> EPC is a nonprofit trade association representing North American manufacturers of emulsion polymers including: Air Products & Chemicals, Inc., BASF Corporation, The Dow Chemical Company, Dow Reichhold Specialty Latex LLC, Eastman Chemical Company, Johnson Polymer, National Starch and Chemical Company, Noveon, Inc., and Rohm and Haas Company.

Emulsion polymers (EPs) are high molecular weight polymers produced by emulsion polymerization that are strategically important products in today's society. EPs are often used over other similarly performing products because of their favorable environmental profile particularly where there is a desire to reduce emissions of volatile organic compounds. Billions of pounds of these products are produced and used in North America and can be found in everyday household items such as paints and coatings, paper and board, adhesives, textiles, construction and carpet backing. EPs are often used in the manufacture of food contact materials and as such are regulated as "indirect food additives."

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<sup>1</sup> Pub. L. 107-188 amending Federal Food, Drug, and Cosmetic Act (FFDCA) (codified at 21 U.S.C. 331 et seq. (2002)).

## Chemical Industry Is Actively Supporting Programs to Enhance Facility Security

The chemical industry has a concerted program underway to promote security at all stages of chemical production, storage and use. As a major component of the chemical industry, the emulsion polymers industry wholeheartedly supports and embraces these initiatives directed at reducing the likelihood and potential impacts that could result from terrorist activities. Members of EPC are also members of the various other more generic chemical associations (including the American Chemistry Council (ACC) and the Synthetic Organic Chemical Manufacturers Council (SOCMA)) who have been working with the Department of Homeland Security and other governmental agencies to minimize the threat of terrorist activities.

The industry, largely through its national associations, has developed guidelines and is currently implementing procedures for enhancing security at its facilities. Of particular note is the Site Security Guidelines for the US Chemical Industry recently developed by ACC, SOCMA and The Chlorine Institute. This guide<sup>2</sup> addresses the same issues covered by FDA's Food Security Preventive Guidance.

Additionally, the emulsion polymers industry, as part of the chemical industry, is required to comply with a wide range of environmental and health and safety regulations intended to minimize the likelihood of a significant large-scale risk of accidental releases to the environment or exposure of workers and the public to hazardous substances. Example regulatory programs include:

**Process Safety Management Standard** – The Occupational Safety and Health Administration (OSHA) Process Safety Management Standard (PSM) [29 CFR 1910.119] requires facilities that have a highly hazardous substance above a certain threshold to implement measures to mitigate hazards, including conducting process hazard analysis and maintaining the mechanical integrity of equipment.

**Worker Training and Safety** - Worker training and safety is another area critical to plant safety and security. The OSHA PSM standard requires employers to train employees on the specific health and safety standards, emergency operations including shutdown, and safe work practices applicable to the employee's job tasks. Additionally, OSHA's Hazard Communication standard requires that the hazards of all chemicals produced or imported are evaluated, and that information concerning their hazards is transmitted to employers and employees.

**Coordination with Emergency Responders** - Under Title III of the Superfund Amendments and Reauthorization Act (SARA), Emergency Planning and Community Right-to-Know Act (EPCRA), facilities that have listed chemicals above a certain threshold quantity are required to prepare and submit a hazardous chemical inventory form to their local emergency planning committee, state emergency response commission, and local fire department. Also, EPCRA

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<sup>2</sup> The Site Security Guidelines for the US Chemical Industry can be downloaded from [www.socma.com](http://www.socma.com).

requires the establishment of Local Emergency Planning Committees (LEPC) to work with industry to develop emergency response plans addressing potential risks from a chemical related accident, to collect and store information provided by facilities; and make the information available to the public. Representatives to the LEPC include individuals from the fire department, emergency management agencies, local health agencies and hospitals, local officials, community groups, media and local businesses.

With all of these initiatives in mind, it is clear that the industry is well aware and appreciates the importance of programs aimed at addressing potential accidents including threats from terrorist activities. It is precisely for this reason, that the industry believes that FDA's has unnecessarily expanded the scope of its proposal beyond what is needed to address the goals and objectives of the Bioterrorism Act.

### **FDA Has Expanded the Scope of the Regulation Beyond Congress's Intent and More Importantly, Beyond What Is Reasonable and Necessary to Protect the Nation's Food Supply**

As noted by FDA, the intent of the registration program is to establish a "central database of all domestic facilities producing food [that] would greatly assist FDA in limiting the effects of a food related emergenc[ies]." Section 305 of the Bioterrorism Act directs FDA to establish regulations that:

*require that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered.* [Emphasis added]

Through the registration provision of the Bioterrorism Act, Congress sought to establish a system that is focused on articles of food that are capable of being consumed in the United States. However, by virtue of FDA's other regulatory authorities to regulate indirect food additives, FDA has elected to define "food for consumption in the United States" in its broadest possible framework and in doing so has included not only food capable of being consumed, *i.e.*, edible foods, but also "substances that can migrate into food from food packaging and other articles that contact food."

EPC believes that applying the registration requirement to facilities manufacturing chemical substances, such as emulsion polymers used on food-contact materials, is contrary to the intent of Congress. More importantly, such a regulatory program has the potential to create a system that will dilute the government's precious resources at facilities that are highly unlikely to be a focal point for bioterrorism and in doing so, will minimize FDA's ability to respond quickly to any real threat to the nation's food supply.

Requiring the registration of facilities that manufacture "substances that can migrate into food" essentially means there is no logical end to the food chain. For example, consider an emulsion polymer that is used in the manufacture of food contact paper. The regulation as proposed would require the registration of the facility manufacturing the food contact paper, but also the facility producing the polymers and arguably the facility producing the monomers. It is difficult to conceive that any benefit

would be derived through the registration or prior notice of import requirements for such facilities. Additionally, there is a significant potential for over regulation and excessive import notification since many chemical suppliers may not be aware whether the ultimate end use of their products are food-contact related.

EPC also questions whether this was in fact FDA's intent. We are aware of discussions at a public meeting between the National Food Processors Association and FDA where Agency officials specifically indicated that the intent of the proposal is for the rule to cover only finished packaging that will be in direct physical contact with food. In response to a question, FDA indicated that the regulations would not cover polymers, additives, or monomers, but only the "immediate" food packaging made from such components. The current language in FDA's proposal, however, goes well beyond and as written, explicitly brings into the registration program chemical manufacturing facilities producing substances that become "components" of food packaging.

For these reasons, EPC respectfully submits that facilities manufacturing substances that are used on food packaging should not be included within the scope of the registration or the prior notice of import regulations. This can be achieved by deleting the phrase "including substances that migrate into food from food packaging and other articles that contact food" from Section 1.227(c)(4).

EPC further believes that FDA should not include within the scope of its Prior Notice of Import regulations, substances that migrate into food from food packaging. In fact, the legislative history suggests that Congress never intended to include food-packaging materials within the scope of the prior notice of import provision. For this reason, EPC also recommends that FDA delete from Section 1.277(c)(3) the phrase "including substances that migrate into food from food packaging and other articles that contact food" and clarify that for purposes of this provision, "food" does not include food-contact materials not yet containing food at the time of importation.

EPC fully supports efforts to promote homeland security and its members have active programs underway to safeguard the men and women who work at America's chemical facilities, the community in which the industry's facilities are located and the downstream users of products. However, we respectfully submit that FDA's proposal to extend the registration and prior notice of import requirements to facilities that manufacture or process chemical substances (such as emulsion polymers) used in the manufacture of food-contact articles, will unduly burden industry, dilute FDA's resources and provide no significant protection against terrorism.

Please do not hesitate to contact me if I can provide any further clarification.

Sincerely,

Robert J. Fensterheim  
Executive Director